

Exhibit A

Exhibit A



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
 Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/245,307 ✓ 02/08/99 ✓ KOZIKOWSKI ✓

A

~~9328-0009-99~~

9328-0009-999

EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 01/17/01

020582

PENNIE &amp; EDMONDS LLP

1667 K STREET NW

SUITE 1000

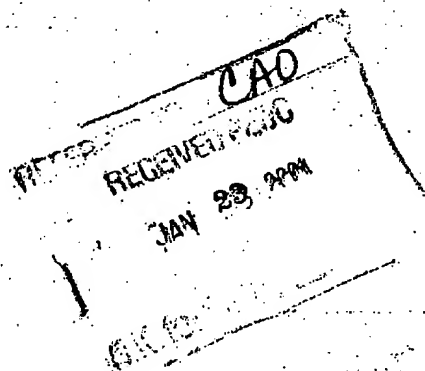
WASHINGTON DC 20006

HM12/0117

*Amendment 4-17-01*  
*Amendment 7-17-01* (2)

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



RECEIVED  
 PENNIE & EDMONDS

JAN 24 2000

S. Singh - 263

CA OFFICE

**Office Action Summary**

Application No.

09/246,307

Applicant(s)

Kozikowski et al.

Examiner

ANISH GUPTA

Group Art Unit

1653

Responsive to communication(s) filed on Oct 23, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

The shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is later, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 C.F.R. 1.136(a).

**Disposition of Claims**

Claim(s) 12-17, 20-28, 31, 32, and 73-81 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 12-17, 20-28, 31, 32, and <sup>73</sup>74-81 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Drawings**

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

**Priority**

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**References**

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application/Control Number: 09/246,307  
Art Unit: 1654

Page 2

### DETAILED ACTION

Applicants amendment filed 10-23-00 is hereby acknowledged. Applicants canceled claims 1-11, 18, 19, 20, 29, 30, and 33-72, amended claims 12-13 and 22, and added claims 73-81.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17, 20-28, 31-32 and 74-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that "A disclosure, as filed, is presumed to be enabled, unless there is reason to objectively doubt the truth of the statement relied on for enabling support." Applicants contend that the Examiner has not provided any explanation for why claims 23-28 and 31-32, drawn to a method of enhancing cognitive function, are not enabled by the specification. The specification provides guidance on how to make the compounds and provides guidance for method of testing compounds with art recognized models that demonstrate the cognition enhancing properties of the compounds. Applicants further assert "that the conclusion and opinions of the prior art are irrelevant, since Examples 8 and 9 of the instant Application demonstrate efficacy of the compound of the invention in art-accepted animal models. Nothing more is required under 35 U.S.C. § 112, first paragraph." Finally Applicants are contending that "Applicants are entitled to a generic claim without exemplifying every possible embodiment of that generic claim." Applicants have also submitted a declaration by Dr. Alan Faden in which it is stated, when making reference to assay method used to demonstrate enhanced cognitive function, that "these assays, alone, demonstrate a high likelihood that the disclosed compounds may be useful as a cognitive enhancing therapy for indication such as Alzheimer's disease." The declaration also states that ample guidance has been provided in the specification and further provides in vitro evidence in the affidavit showing that the compounds of the claimed invention block neural cell death after insults and in vitro model of ischemia(stroke)-oxygen deprivation and excitotoxic (glutamate-induced) free radical induced injuries. In the

Application/Control Number: 09/246,307  
Art Unit: 1654

Page 3

declaration, Dr. Faden also states, on page 4, that "[t]he claims in the accompanying response have been modified to reflect the fact that we only claim head injuries, spinal cord injury, and stroke."

Applicant's arguments filed 10-23-00 and the Declaration by Dr. Faden have been fully considered but they are not persuasive.

First, as to the scope of the claims, the claims state a method of treating a neurological disorder or a CNS injury, said method comprising the step of administering and effective amounts of compound of claim 12. The claims are broad in terms of the treatment of the neurological disorders and thus are inclusive of disorders such as ALS, Parkinsons, Alzheimer's. The claims are not solely limited to head injuries, spinal cord injury, and stroke as Applicants contend. If Applicants intend such limitation, then Applicants are requested to amend the claims accordingly.

It is still the position that the specification does not provide ample guidance to the practice the claimed invention. First the working examples provided in the declaration are drawn to the treatment of free radical and oxygen deprivation injuries. The art recognizes that neural cells can and do recover from such disorders. However, the specification nor the declaration provides any guidance as to the neuroprotection from disorders such as Alzheimer's, Parkinsons, and ALS. Applicants argue that the Examiner has not provided any evidence that the method claimed are not enabled. However, in the previous office action the reference of Patel was cited to indicate the state of the art for therapies in the treatment of Alzheimer's. The reference concludes, even after reviewing various known Alzheimer therapies, that the search for an effective cognition-enhancing therapy has so far proved elusive (see page 90). Applicants argue that this reference is irrelevant in light of the examples cited in the specification. However, the working examples do not establish the treatment of age associated impairments in performance on cognitive and memory task as a result of the presence of extracellular deposits of amyloid-beta. The examples recited in the specification are not art recognized animal models for the measurement of cognition enhancement as a result of Alzheimer. The working examples in specification and in the declaration fail to provide the correlation between traumatic brain injury and Alzheimer's. Finally, Applicants have asserted that Applicants are not required to provide guidance or working examples of every possible embodiment of the invention. Applicants are however reminded that the MPEP states that "[p]roof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the

Application/Control Number: 09/246,307  
Art Unit: 1654

Page 4

genus as a whole without undue experimentation." M.P.E.P 2164.02. In this case the art indicates undue experimentation for the treatment of neuroprotection and cognitive enhancement as a result of Alzheimer's

The Rejection is Maintained.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1-7 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by Stadler et al. (FR 1583797) is hereby withdrawn.

**New Grounds For Rejection**

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12-17, 20-28, 31-32, 73-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of providing neuroprotection. However, the claims do not recite to whom such a compound is being administered to. Applicants are requested to amend the claims to recite "A method of providing neuroprotection to a person in need thereof, for time and under conditions to provide neuroprotection, said method . . . "

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Application/Control Number: 09/246,307  
Art Unit: 1654

Page 5

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Anish Gupta

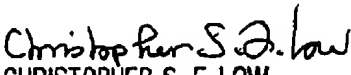
  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Exhibit B

Exhibit B





## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/246,307	02/08/1999	ALAN P. KOZIKOWSKI	9928-0009-99	6016

7590

04/04/2002

SCULLY, SCOTT, MURPHY & PRESSER  
400 GARDEN CITY PLAZA  
GARDEN CITY, NY 11530

EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/246,307

Applicant(s)

KOZIKOWSKI ET AL

Examiner

Anish Gupta

Art Unit

1653

**-The MAILING DATE of this communication appears on the cover sheet with the correspondence address -****THE REPLY FILED 7-11-01 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.**

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 mont months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: 73.Claim(s) rejected: 12-17,20-28,31,32 and 74-81.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s).
10. ☐ Other: \_\_\_\_\_

*Christopher S. F. Low*  
 CHRISTOPHER S. F. LOW  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 1600